

**IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF PENNSYLVANIA**

**IN RE: SUBOXONE (BUPRENORPHINE
HYDROCHLORIDE AND NALOXONE)
ANTITRUST LITIGATION**

)
) **MDL NO. 2445**
)
)

) **Master File No. 2:13-md-2445-MSG**
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THIS DOCUMENT RELATES TO:

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) *Amneal Pharms. LLC v. Indivior, Inc. et al.*
)

**AMNEAL PHARMACEUTICALS LLC'S OPPOSITION TO
INDIVIOR, INC.'S PARTIAL MOTION TO DISMISS**

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INTRODUCTION

Plaintiff Amneal Pharmaceuticals LLC (“Amneal”) opposes Defendant Indivior, Inc.’s (f.k.a. as Reckitt Benckiser Pharmaceuticals, Inc.) (hereinafter “Reckitt”) Partial Motion to Dismiss (ECF 212).¹ Amneal respectfully requests that the Court deny Reckitt’s Motion as set forth below. Amneal has pleaded more than sufficient facts to support its antitrust and false advertising claims. Reckitt’s attachment of over a dozen exhibits to support its arguments demonstrates that the Motion presents questions of fact improper for Rule 12 dismissal. To the extent that the Court finds any deficiencies in Amneal’s Complaint, Amneal respectfully requests leave to amend pursuant to Fed. R. Civ. P. 15 as Amneal does not believe that Reckitt has raised any challenges that cannot be overcome by amendment.

As alleged, Reckitt first obtained monopoly power in the market for buprenorphine naloxone (“Bu-Na”), a leading prescription medication for opiate addiction, by obtaining orphan drug status, asserting to the FDA, ironically, that a drug that now generates over \$1 billion per year was so economically risky that Reckitt deserved to be free of generic competition for seven years. Amneal alleges that Reckitt cleverly, but illegally, preserved and extended its orphan drug monopoly by a carefully orchestrated, anticompetitive scheme to shift the Bu-Na market from tablets to a film formulation – which enjoys patent exclusivity for many years – just as generic competition was about to begin for tablets.

The Complaint alleges, in significant detail, Reckitt’s anticompetitive tactics in support of its overarching scheme to move the market from tablets to film, including:

¹ Amneal does not oppose the dismissal of claims “against the former corporate name,” Reckitt Benckiser Pharmaceuticals, Inc., based on the representation that it is “merely the former name of Indivior, Inc., and not a separate entity.” See ECF 212-1 at 1 n.1. However, as the complaint and related documents largely involve the former entity, Amneal intends to refer to the primary defendant as “Reckitt” to avoid confusion, including of any jury.

- Affirmatively pledging to the FDA and putative generic entrants that Reckitt would cooperate in developing a single, shared safety program mandated by the FDA to benefit the patient community and healthcare system, when Reckitt never had any intent to do so;
- Submitting a sham Citizen Petition to the FDA asserting, without scientific basis, that the tablets – which Reckitt had sold exclusively for 10 years – were suddenly unsafe due to packaging concerns;
- Falsely representing to health care providers and patients that the film is safer than tablets and disparaging the tablets as unsafe; and
- Inducing health care providers to write prescriptions for the patent-protected film by using illegal payments and threats.

Reckitt timed the elements of this “product hopping” scheme to exert maximum delay of generic entry and “hop” as much of the market as possible from tablets to film. Reckitt’s scheme delayed Amneal’s ANDA approval and shrank the available market for Amneal’s generic Bu-Na tablet once approved, resulting in significant lost sales both before and after generic entry.

Reckitt’s Motion raises classic questions of fact, such as causation, which the Court has already found improper for Rule 12. Reckitt also asks the Court to pull threads out, one at a time, from the tapestry of Reckitt’s monopolistic conduct. The Supreme Court and the Third Circuit have instructed otherwise – that antitrust liability for an illegal scheme depends on the monopolist’s conduct taken as a whole, rather than each aspect in isolation, even when individual aspects may not be actionable alone. *See, e.g., Cont’l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 698-699 (1962); *LePage’s Inc. v. 3M*, 324 F.3d 141, 162 (3d Cir. 2003) (*en banc*).

Thus, the Motion should be denied and Reckitt required to participate in discovery fleshing out the scope of its illegal scheme.

BACKGROUND ALLEGATIONS

Suboxone is the brand-name combination of active pharmaceutical ingredients buprenorphine and naloxone (also known as “Bu-Na”), a leading treatment of opiate dependency, such as addiction to heroin and opioid-based prescription painkillers. *See Amneal* Dkt. No. 1 (“Compl.”) at ¶ 2. From 2002 to the present, Reckitt has manufactured and sold Suboxone in the U.S. *Id.* Reckitt sells both film and tablet versions of Suboxone around the world, but announced that it would discontinue sales of the tablet in the U.S. just prior to generic entry for that product. *Id.* at ¶¶ 2, 112. While the tablet and film products are clinically interchangeable, as Amneal alleges, the film is *inferior* in important ways relating to safety and diversion. *Id.*; *see also id.* at ¶¶ 104-108.

In 2002, Reckitt obtained seven-year “orphan drug” exclusivity on the sale of Suboxone tablets in the U.S. by representing to the FDA that it was *unlikely to recover its costs* on the product without exclusivity. *See id.* at ¶¶ 3, 30-32. Suboxone rapidly became the dominant drug prescribed in the U.S. for the treatment of opioid dependence outside a clinical setting, now with annual sales of \$1 billion, constituting the vast majority of Reckitt’s revenues. *Id.* at ¶¶ 2, 56.

As the end of its U.S. exclusivity of tablets neared in 2009, Reckitt engaged in a “multi-pronged, anticompetitive scheme to delay generic entry for the tablet” and “hop” patients and prescribers to the film version of the product, for which Reckitt claims exclusive patent protection until 2030. *Id.* at ¶ 3. Reckitt’s investor reports openly acknowledged that Reckitt’s conduct was designed to, and did, “mitigate the impact” of generic entry to the tablet market by extending and maintaining Reckitt’s “Suboxone franchise.” *Id.*

One anticompetitive tactic Reckitt used to delay generic entry was deception relating to a safety program required by the FDA for all oral buprenorphine products. *Id.* at ¶ 4; *see also id.* at ¶¶ 66-89. The program, referred to as Risk Evaluation and Mitigation Strategies, or “REMS,” includes medication guides, communication plans for doctors and patients, and other elements required by the FDA to assure safe use in order to ensure that the benefits of the covered drug outweigh its risks. *Id.* at ¶ 4.

Because the FDA required a REMS program for Suboxone tablets, all generic applicants for that product were required to join with Reckitt to develop a “single, shared REMS system” – also known as an “SSRS” – to gain approval. *Id.* The FDA advised generic applicants on January 6, 2012 that an SSRS was required and expected that the SSRS would be completed within four months as required by statute. *Id.* at ¶¶ 70-71. Both the FDA and statute required an SSRS “in the interest of public health and to reduce the burden on the healthcare system of multiple unique REMS programs.” *Id.* at ¶¶ 70, 75. In fact, the FDA repeatedly advised the parties that “it had never before approved a waiver for a separate REMS program.” *Id.* at ¶ 75.

With this knowledge, Reckitt “falsely represented to the FDA and generic manufacturers that it would work cooperatively to develop an SSRS when, in fact, Reckitt had no intention of cooperating.” *Id.* at ¶ 5. By falsely representing that it would cooperate in creating an SSRS, Reckitt “delayed generic entry and became privy to information that it would otherwise not have known, which it used to its anticompetitive advantage.” *Id.* at ¶ 6. Reckitt knew, for example, the likely timeline and proposed program content for generic SSRS waiver request submissions, enabling Reckitt to craft other schemes designed to impede generic entry, such as filing a sham “Citizen Petition” with the FDA on the eve of waiver requests. *Id.*; *see also id.* at ¶¶ 90-101.

Reckitt's sham Citizen Petition, a related aspect of the product hopping scheme, expressly requested that "the FDA *refrain[] from approving* any generic Suboxone tablet ANDA" until after resolving purported public health issues involving the tablet. *Id.* at ¶¶ 7-10 (emphasis added); *see also id.* at ¶¶ 41-42, 91-92. The requests set forth in Reckitt's Petition were "objectively baseless and subjectively intended only to delay and thwart the ability of generic Bu-Na tablets to compete with Reckitt's Suboxone products." *Id.* at ¶ 7; *see also id.* at ¶¶ 41-42, 91-92.

As a result of the sham Citizen Petition, "generic entry was delayed by another five months as the FDA was forced to consider the Petition, which further delayed consideration and approval of a waiver-based REMS." *Id.* at ¶ 92; *see also id.* at ¶ 97. That added delay, in turn, "ensured [Reckitt's] continued monopoly in the market while the Petition was being evaluated and, along with Reckitt's deceptive REMS conduct, facilitated Reckitt's product-hopping scheme." *Id.* at ¶ 97.

On February 22, 2013, more than nine months after the FDA expected completion of an SSRS, and nearly five months after Reckitt filed its Citizen Petition, the FDA issued a decision denying Reckitt's Citizen Petition in its entirety. *Id.* at ¶ 98; *see also id.* at ¶¶ 99-101. The FDA correctly determined that it did not have authority to grant Reckitt's requested relief, that Reckitt did not provide evidence supporting its assertions, and that Reckitt improperly sought a determination that its product was removed from the market for safety reasons despite continuing to sell the product. *Id.* at ¶ 11; *see also id.* at ¶¶ 98-101.

The FDA further stated that, "[t]he *timing* of Reckitt's September 2012 announcement that it would discontinue marketing of the tablet product because of pediatric exposure issues, given its close alignment with the period in which generic competition for this product was

expected to begin, cannot be ignored.” *Id.* at ¶ 12 (emphasis added). In an unprecedented move, the FDA referred the matter to the Federal Trade Commission (“FTC”), an agency with “the administrative tools and the expertise to investigate and address anticompetitive business practices.” *Id.*; *see also id.* at ¶ 101. As Reckitt has acknowledged, the FTC has undertaken an investigation of Reckitt’s conduct, including “alleged involvement in a scheme to delay FDA approval of generic versions of [the] Suboxone Tablet.”² *Id.* at ¶ 17.

On the same day that it denied Reckitt’s Citizen Petition, the FDA granted the waiver-based REMS, and approved Amneal’s ANDA for tablet sales. *Id.* at ¶ 13.

In anticipation of generic entry and during the delay period caused by the REMS deception and sham Citizen Petition, Reckitt undertook other anticompetitive measures to support its scheme to shift the market from tablets to film and minimize the impact of generic entry, including false and disparaging messaging to discourage physicians from writing prescriptions for tablets under the pretext of alleged safety and diversion concerns, price manipulation (“significantly” raising the price of brand tablets while keeping film relatively lower), improper penalties for doctors who did not push their patients to the film product and rewards for doctors who did, and offering payments and other benefits to doctors if they switched prescriptions from tablets to film in violation of the Medicaid-Medicare Anti-Kickback Statute.³ *Id.* at ¶¶ 14, 16, 111.

² Reckitt has also disclosed that “a contingent of states, led by the Wisconsin State Attorney General, have initiated a coordinated investigation into the same conduct that is the subject of the FTC investigation and the [Multidistrict] Class Action litigation.” Compl. at ¶ 17.

³ In addition to the FTC and State AG antitrust investigations, Reckitt has disclosed investigations by two U.S. Attorney Offices relating to “the promotion, marketing and sale” of Suboxone film and tablets and “remuneration of physicians,” and the execution of a “search warrant” on Reckitt’s headquarters in Virginia and “searches of the homes of four field-based employees.” *See* Compl. at ¶ 17.

Amneal alleges that Reckitt's anticompetitive scheme "both *delayed* entry into the market by generic competitors and *hindered* competition after generic entry finally occurred," which cost Amneal, "a pioneer generic in this market, substantial market share and lost sales." *Id.* at ¶

1. Amneal specifically alleges that its injury would not have occurred "but for" Reckitt's anticompetitive conduct and false statements. *See, e.g., id.* at ¶¶ 18, 19, 122-124.

Based on its allegations, Amneal asserts claims for monopolization and attempted monopolization under Section 2 of the Sherman Act, and false advertising under the Lanham Act. *See* Compl. at ¶¶ 1, 125-140. Reckitt challenges those claims as set forth below.

ARGUMENT

1. Reckitt's REMS Conduct is Properly Part of the Monopolization Scheme.

Reckitt first seeks to dismiss Amneal's REMS allegations, arguing that they are "identical" to those asserted in support of a claim made by the class Plaintiffs that the Court previously dismissed. ECF 212 at 1 ¶ 1. In its prior decision, the Court held that, under antitrust law, Reckitt had no duty to deal with its generic competitors on the REMS. *See* ECF 97 at 26.

Amneal's theory involving Reckitt's REMS conduct is not foreclosed by the Court's duty to deal ruling. As set forth below, Amneal's REMS allegations (1) state an actionable claim of anticompetitive *deception* under controlling Third Circuit precedent, which the Court did not previously address; and (2) are properly included as part of an overarching illegal scheme, regardless of whether the conduct is actionable standing alone.

Under Third Circuit law, deceptive conduct undertaken to obtain or extend a monopoly constitutes a violation of Section 2. *See W. Penn Allegheny Health Sys., Inc. v. UPMC*, 627 F.3d 85, 109-10 n.14 (3d Cir. 2010) (false statements about a rival's financial health combined with other anticompetitive acts actionable under Section 2); *Broadcom Corp. v. Qualcomm Inc.*, 501

F.3d 297, 313-14 (3d Cir. 2007) (intentionally false promise to license essential proprietary technology on fair and reasonable terms “is actionable anticompetitive conduct”); *LePage’s Inc.*, 324 F.3d at 152-54 (recognizing deception as form of monopolistic conduct).⁴

Further, as the Third Circuit has made clear, allegations of anticompetitive deceptive conduct are evaluated under a *different standard* than an alleged refusal to deal. *See Broadcom*, 501 F.3d at 316-17. In *Broadcom*, a seminal case on this topic, the Third Circuit held that deceptive statements to rivals, made in a context where recipients reasonably expect not to be misled, states a claim for monopolization. *See* 501 F.3d at 312. In that case, Broadcom alleged that Qualcomm, a competitor, committed to members of a standards-setting organization, including Broadcom, that it would license its patents covering a standard on fair, reasonable and non-discriminatory (“FRAND”) terms, knowing that commitment to be false. *Id.* at 313. Broadcom alleged that, once Qualcomm succeeded in getting its patented technology included in the standard, thereby gaining market power for the technology, it then reneged on its false FRAND commitment. *Id.* The district court initially dismissed the complaint, finding that “the basic allegation is that Qualcomm’s conduct amounts to a refusal to deal fairly,” and rejecting

⁴ Other Circuits have also found deception that extends or creates monopoly power actionable under Section 2. *See, e.g., United States v. Microsoft Corp.*, 253 F.3d 34, 76-77 (D.C. Cir. 2001) (actionable deception of Java developers based on Microsoft’s “public commitment” that software developed using Microsoft’s tools would run on other platforms when they would only run on Microsoft’s platform); *Conwood Co., LP v. U.S. Tobacco Co.*, 290 F.3d 768, 790-91 (6th Cir. 2002) (misrepresentations of sales activity by category captain that limited the ability of rivals to sell through retailers found anticompetitive); *Caribbean Broad. Sys., Ltd. v. Cable & Wireless PLC*, 148 F.3d 1080, 1087 (D.C. Cir. 1998) (“[T]he allegations made here – namely, that defendants made fraudulent misrepresentations to advertisers and sham objections to a government licensing agency in order to protect their monopoly – bring the defendants’ conduct well within that concept [of anticompetitive conduct].”); *see also Research In Motion Ltd. v. Motorola, Inc.*, 644 F. Supp. 2d 788, 796 (N.D. Tex. 2008) (motion to dismiss antitrust claims rejected where complaint alleged that defendant “obtained its position of power in the market not as a consequence of a superior product, business acumen or historic accident, but by misrepresenting its intentions”).

the claim as an “impermissible attempt to extend the Supreme Court’s refusal-to-deal jurisprudence.” *Id.* at 316. The Third Circuit reversed, holding that Broadcom’s allegations stated an actionable offense for deception under Section 2. *Id.* at 316-17 (“This case does not involve a refusal to deal.”). According to the Third Circuit, an actionable monopoly deception claim lies where alleged misrepresentations occur in a “consensus-oriented environment” in which “participants are less likely to be wary of deception and may not detect such conduct and take measures to counteract it.”⁵ *Id.* at 312; *see also id.* at 314.

Similarly here, Amneal alleges that “Reckitt falsely represented to the FDA and generic manufacturers that it would work cooperatively to develop an SSRS when, in fact, Reckitt had no intention of cooperating.” Compl. at ¶ 5; *see also id.* at ¶¶ 6-7, 70-88. Reckitt did so in the context of negotiations overseen by a federal agency, involving a statutorily required program designed for patient safety, a context in which deception would not be expected. *See Broadcom*, 501 F.3d at 312. Specifically, the complaint includes, *inter alia*, allegations that:

- (1) On January 6, 2012 the FDA issued a letter to Amneal and all other sponsors of pending ANDAs for generic Suboxone tablets stating that, “before FDA can continue review of your ANDA you must submit a proposed REMS as an amendment to your ANDA,” Compl. at ¶ 70;
- (2) The FDA “determined that a single, shared system” for all buprenorphine products was needed “in the interest of public health and to reduce the burden on the healthcare system of multiple unique REMS programs,” *id.* at ¶ 70;
- (3) “The FDA directed Amneal and others to collaborate with Reckitt on the proposal because the FDA would not approve the ANDAs without an FDA-approved SSRS,” *id.*;

⁵ None of the policy objections to extending the refusal to deal jurisprudence apply when a monopolist is alleged to have used deception to maintain monopoly power. *See Verizon Commc’ns Inc. v. Law Offices of Curtis V. Trinko*, 540 U.S. 398, 407-408 (2004). For instance, it would not lessen the monopolist’s or any rival’s incentive to invest in economically beneficial facilities if it may be held liable for deception. Rather, compelling monopolists to not engage in deception only lessens the monopolist’s incentive to deceive, a positive result.

- (4) “[T]he FDA made clear that it wanted a single shared system and would frown on any separate shared REMS,” and the FDA “noted that it had never before approved a waiver for a separate REMS program[.]” *id.* at ¶ 75;
- (5) Reckitt never intended to comply with the SSRS mandate, *id.* at ¶ 73;
- (6) Reckitt did not tell the FDA or generic manufacturers that it never intended to comply with the SSRS mandate, *id.* at ¶¶ 73-74;
- (7) Reckitt explicitly and falsely represented to the FDA and generic manufacturers that it would cooperate and constructively engage in the development of the SSRS, *id.* at ¶¶ 76-79, 81, 85, 86;
- (8) By falsely leading the FDA and generic manufacturers to think that it would constructively engage in the development of the SSRS, Reckitt was able to engage in other tactics designed to slow the development of the SSRS, *id.* at ¶¶ 73-83;
- (9) “[H]ad Reckitt truthfully represented that it never intended to participate constructively in the SSRS at the outset [i.e., on or around on January 6, 2012], the generic sponsors would have been able to seek and obtain a waiver of the requirement to develop the program involving Reckitt immediately, rather than waiting until October 3, 2012[.]” *id.* at ¶ 86; *see also id.* at ¶ 87; and
- (10) As a result, “Reckitt’s deception delayed generic entry past the date when entry otherwise would have occurred[.]” *id.* at ¶ 88.

These deception allegations are not foreclosed by the Court’s prior ruling. *See* ECF 97 at 26. The Court analyzed the class Plaintiffs’ stand-alone REMS claim under a duty to deal standard, not deception. *Id.* The Court explained that the “duty to deal” under antitrust law is an “exception” to the general proposition that a monopolist does not have a duty to assist its competitors. *Id.* Thus, under the Court’s ruling, Reckitt might not be found liable under antitrust law solely for *refusing to participate* in the REMS process. But that is not what Reckitt is alleged to have done here. Rather, for many months, Reckitt *falsely represented* to the FDA and generic manufacturers, including Amneal, that it would cooperate in the REMS process, thereby delaying requests for waivers of the SSRS requirement – which the FDA had never before granted – and ultimately delaying generic approval and entry into the market. The deception has

clear anticompetitive consequences. Materials recently produced to Amneal in discovery provide a factual basis for this theory. Such deceptive conduct is actionable under Section 2 and is neither addressed nor foreclosed by the Court's prior ruling.

Further, unlike the stand-alone claim dismissed in the Court's prior ruling, Amneal alleges that Reckitt's REMS conduct was just *one facet* of an overarching anticompetitive scheme to monopolize the Bu-Na market. *See* Compl. at ¶¶ 3-4. That aspect of the scheme need not stand alone as an actionable claim to be alleged as part of a larger plan.⁶

The Supreme Court and Third Circuit have repeatedly held that anticompetitive conduct underlying an alleged monopolistic scheme should be taken as a whole, not taken apart. *See Cont'l Ore Co.*, 370 U.S. at 698-99 (directing federal courts not to "approach [antitrust] claims as if they were . . . completely separate and unrelated lawsuits."); *LePage's*, 324 F.3d at 162 (antitrust liability depends on "the monopolist's conduct taken as a whole rather than . . . each aspect in isolation."); *Big Apple BWM, Inc. v. BMW of N. Am., Inc.*, 974 F.2d 1358, 1364-1365 (3d Cir. 1992) ("That evidence should be analyzed as a whole, rather than compartmentalized, to determine whether it supports an inference of [an antitrust violation]."). As the Supreme Court explained in *Continental Ore*:

In cases such as this, plaintiffs should be given the full benefit of their proof without tightly compartmentalizing the various factual components

⁶ *See, e.g., Rochester Drug Coop. v. Braintree Labs.*, 712 F. Supp. 2d 308, 318 (D. Del. 2010) ("The court need not, and declines to, analyze whether each facet of [the alleged monopoly] scheme constitutes a separate antitrust violation."); *In re Gabapentin Patent Litig.*, 649 F. Supp. 2d 340, 358-59 (D.N.J. 2009) ("[C]ourts have allowed antitrust plaintiffs to pursue such claims even in the absence of allegations that each of the scheme's predicate actions was independently violative of antitrust laws."); *Abbott Labs v. Teva Pharm. USA, Inc. ("Tricor")*, 432 F. Supp. 2d 408, 428 (D. Del. 2006) ("Defendants argue that Plaintiffs' allegations of an overall scheme to monopolize fail to state a claim, because, if liability is not found based on individual acts, then none can be found on the acts taken together. That argument is contrary to law.") (internal citations omitted).

and wiping the slate clean after scrutiny of each.... [T]he duty of the jury was to look at the whole picture and not merely the individual figures in it.

370 U.S. at 699; *see also* *Swift & Co. v. U.S.*, 196 U.S. 375, 396 (1905) (Holmes, J.) (“It is suggested that the several acts charged are lawful, and that intent can make no difference. But they are bound together as the parts of a single plan. The plan may make the parts unlawful . . . The unity of the plan embraces all the parts.”).⁷

Here, Amneal alleges that Reckitt’s REMS conduct was “[o]ne anticompetitive tactic” in a “multi-pronged, anticompetitive scheme to delay generic entry for the tablet and ‘hop’ patients and prescribers to the film version of the product its scheme to delay generic entry in the market.” *See* Compl. at ¶ 3; *see also id.* at ¶¶ 66-89. For instance, by falsely representing that it would participate in good faith, Reckitt delayed the generic requests for a waiver from the SSRS requirement, and gained knowledge regarding the timing and content of those requests. *Id.* at ¶ 6. Reckitt used that information to strategically time and execute its sham Citizen Petition,

⁷ District Courts in the Third Circuit consistently follow the *Continental Ore* instruction. *See, e.g., Microsoft Mobile, Inc. v. Interdigital, Inc.*, No. 15-723-RGA, 2016 U.S. Dist. LEXIS 49498, at *10-12 (D. Del. Apr. 13, 2016); *Rochester Drug*, 712 F. Supp. 2d at 318 (“Plaintiffs may make their antitrust case by establishing an ‘overall scheme’ to forestall generic competition. ‘[C]ourts must look to the monopolist conduct taken as a whole rather than considering each aspect in isolation’; ‘[if plaintiffs] can allege that a series of actions, when viewed together, were taken in furtherance and as an integral part of a plan to violate the antitrust laws, that series of actions, as an overall scheme, may trigger antitrust liability.’”) (quoting *In re Gabapentin Patent Litig.*, 649 F. Supp. 2d at 358-59 (“If a plaintiff can allege that a series of actions, when viewed together, were taken in furtherance and as an integral part of a plan to violate the antitrust laws, that series of actions, as an overall scheme, may trigger antitrust liability.”)); *Tricor*, 432 F. Supp. 2d at 428 (“Plaintiffs are entitled to claim that individual acts are antitrust violations, as well as claiming that those acts as a group have an anticompetitive effect even if the acts taken separately do not.”).

which it on filed September 25, 2012, just one week before the generic sponsors submitted their SSRS waiver requests, thereby maximizing the delay of generic entry.⁸ *Id.* at ¶¶ 5-6, 88.

While generics were kept out of the market due to the REMS deception and Citizen Petition, Reckitt had free reign to engage in other deceptive and anticompetitive conduct to switch the market from tablet to patent-protected film, such as false and disparaging messaging and price manipulation (significantly raising the price of tablets without fear of competition). *See Compl.* at ¶¶ 14-16, 111. For instance, Reckitt made a noisy withdrawal of its tablet product, announcing that it had determined Bu-Na tablets to be “unsafe” and would remove them from the market, thereby “sow[ing] confusion in the market as to the availability and propriety of prescribing generic tablets.” *Id.* at ¶ 112. As proof that the scheme worked, according to Reckitt’s own reports, in the period spanning the REMS and Citizen Petition delays, Reckitt hopped an astonishing 20% (or more) of the market from tablets to film. *See id.* at ¶¶ 113-14.

Thus, Amneal’s claim involves more than a simple refusal to deal by Reckitt. It involves an intentional effort to dupe the FDA and competitors as part of an overarching scheme designed to delay generic entry. In Amneal’s view, Reckitt’s REMS conduct is actionable and may be asserted in support of a Section 2 monopolization claim under controlling Third Circuit law.

2. The Sham Citizen Petition is Properly Part of the Monopolization Scheme.

Reckitt also argues that Amneal’s sham Citizen Petition allegations should be dismissed because “Amneal makes no allegation that FDA violated its statutory obligation” under Section

⁸ But for the Citizen Petition, Amneal alleges that a REMS would have been approved sooner. For example, the FDA expected that a new REMS – not based on Reckitt’s REMS materials – could be developed and “up and running” within two months. *Compl.* at ¶ 81. But “[a]s a result of the sham [Citizen] Petition, generic entry was *delayed by another five months* as the FDA was forced to consider the Petition, which further delayed consideration and approval of a waiver-based REMS.” *Id.* at ¶ 92 (emphasis added); *see also id.* at ¶¶ 90, 98.

505(q) not to delay generic approvals based on a citizen petition. ECF 212 at 2, ¶ 3. Again, Reckitt's position should be rejected.

Amneal's complaint is flush with allegations showing that Reckitt's Citizen Petition was a sham – *i.e.*, that it was objectively baseless and subjectively filed with the anticompetitive intent of delaying generic entry – which Reckitt does not seriously challenge. *See* Compl. at ¶¶ 7-13, 90-101. Amneal also repeatedly and sufficiently alleges the Citizen Petition was part of the overall monopoly scheme, delaying both the review and approval of the waiver-based REMS and the pending ANDAs. *See* Compl. at ¶ 7 (“[T]he FDA refrained from approving generic versions of Bu-Na until after resolving the purported public health issues raised in the Citizen Petition.”); *id.* at ¶ 92 (“As a result of the sham Petition, generic entry was delayed by another five months as the FDA was forced to consider the Petition, which further delayed consideration and approval of a waiver-based REMS.”); *id.* at ¶ 97 (“By submitting the Citizen Petition, Reckitt ensured a delay in the review and approval of the BPMG waiver-granted REMS and in the approval of the generic ANDAs.”). Amneal further alleges that the time, resources, and expense required from the FDA in responding to citizen petitions, particularly those like Reckitt's making claims about public health and safety, inevitably cause delay. *See id.* at ¶ 42.

In arguing that Amneal did not expressly allege that the FDA “violated” a statutory duty not to delay ANDAs, Reckitt again “place[s] form over substance,” just as the Court found in rejecting Reckitt's identical challenge to the class Plaintiffs' allegations. *See* ECF 97 at 33. The Court further found that an FDA ruling on another citizen petition, submitted as an exhibit by Reckitt in support of its motion to dismiss the class Plaintiffs' claims, showed that “delays still occur despite the mandate of 28 U.S.C. § 355(q)(1)(A).” *Id.*

Many other courts have also held that citizen petitions may cause delay, even despite Section 505(q). *See United Food & Commercial Workers Local 1776 & Participating Emp'rs Health & Welfare Fund v. Teikoku Pharma USA, Inc.*, 74 F. Supp. 3d 1052, 1062 n.13 (N.D. Cal. 2014) (“The FDA typically addresses active Citizen Petitions before approving the related ANDA.”); *In re Skelaxin Antitrust Litig.*, No. 1:12-MD-2343, 2013 WL 2181185, at *20 n.14, 33 (E.D. Tenn. May 20, 2013) (denying motion to dismiss and finding that there was a cognizable dispute regarding the effectiveness of the changes brought by FDCA Section 505(q)); *see also Roxane Labs., Inc. v. Smithkline Beecham Corp.*, No. 09–CV–1638, 2010 WL 331704, at *1 (E.D. Pa. Jan. 26, 2010) (“Because citizen petitions can delay a generic drug’s approval, they are open to abuse by pharmaceutical companies attempting to prolong their monopoly in the market.”); *Spear Pharm., Inc. v. William Blair & Co., LLC*, 610 F. Supp. 2d 278, 285 (D. Del. 2009) (“Congress has recognized that the Citizen Petition process is often abused to delay the introduction of generic drugs.”)).

In addition, as the Court has already found, Third Circuit case law “makes clear that the causal connection is not severed [by a government actor’s failure to follow proper procedures] *if the government actor’s decision is induced by the defendant’s deception or wrongful conduct.*” *See* ECF 152 at 4-5 (citing *Egervary v. Young*, 366 F.3d 238, 250 (3d Cir. 2004)) (emphasis added). In this regard, it cannot be ignored that, as alleged, Reckitt specifically requested that the FDA “refrain from approving” any generic ANDAs while the FDA evaluate what Reckitt argued were issues of health and safety involving the possibility of pediatric death. *See* Compl. at ¶¶ 8-9, 83. Reckitt cannot now point to the FDA as an “intervening cause” of the delay when Reckitt specifically requested that relief in its Citizen Petition.

Again, Reckitt’s Citizen Petition arguments should be denied.

3. Amneal Has Pleaded Antitrust Injury Caused by Reckitt's Delay Tactics.

Reckitt further seeks to dismiss Amneal's delay allegations on the basis that Amneal "fail[s] to allege facts showing that [it] would have launched its product at an earlier time but-for Reckitt's conduct." ECF 212 at 1, ¶ 2. In particular, relying on exhibits that present questions of fact, Reckitt argues that amendments to Amneal's ANDA, not Reckitt's misconduct, caused the alleged delay and any resulting injury. ECF 212-1 at 13. Reckitt's argument should be rejected.

As the Court has already found, and other case law makes clear, alleged delays in ANDA approvals involve "classic factual issue[s]" improper for a Rule 12 motion. *See* ECF 97 at 33-34 ("As to Reckitt's argument that any delays in approval of the ANDA were due to amendments made by the Generics themselves, this is a classic factual issue that is properly determined by a fact finder."); *see also In re Flonase Antitrust Litig.*, 798 F. Supp. 2d 619, 627 (E.D. Pa. 2011) (citing *Callahan v. A.E.V., Inc.*, 182 F.3d 237, 257 (3d Cir. 1999) ("[D]eclining to rule on causation in an antitrust case [. . .], holding instead that causation was an issue[] of fact best left to the jury.")); *In re Lipitor Antitrust Litig.*, No. 3:12-CV-2389 PGS, 2013 WL 4780496, at *24 (D.N.J. Sept. 5, 2013) ("[C]ausation is generally a factual issue, and particularly [. . .] where Defendants contest the allegation that generic competition would have and could have entered the market sooner but for Defendants' conduct.").

Here, Amneal specifically, and repeatedly, alleges that Reckitt's conduct delayed generic entry into the market, and that Amneal would have made sales "but for" Reckitt's anticompetitive "delay tactics" detailed in the complaint, including its REMS deception and sham Citizen Petition. *See* Compl. at ¶¶ 122, 123. For example, in a section headed "Harm to Amneal," Amneal alleges: "Specifically relating to the profits lost by Amneal because of its delayed entry into the Bu-Na market, *but for Reckitt's deceptive conduct in connection with the*

REMS and its sham Citizen Petition, Amneal would have made substantial sales of its generic product. The profits on those sales have been lost because of Reckitt's improper delay tactics." *Id.* at ¶ 123 (emphasis added); *see also id.* at ¶ 122 ("Amneal was injured by Reckitt's anticompetitive conduct, as alleged above, through . . . lost sales during the period that its ANDA was delayed by Reckitt's conduct. . . .").

The Court has already found that the class Plaintiffs' nearly identical allegations stated an actionable claim of delay and should do the same here. *See* ECF 97 at 33 ("I find that the complaints plausibly allege that the Citizen Petition caused antitrust injury by delaying Generic entry into the market. The complaints state that Reckitt filed the Citizen Petition for the purpose of delaying Generic competition, and but for the filing of the Citizen Petition, 'competitors would have begun marketing generic version[s] of Suboxone well before they actually did.'").

Other courts have repeatedly found facts similar to those alleged by Amneal, such as where an ANDA was approved on the same day the FDA denied an alleged sham citizen petition, sufficient under Rule 12. *See, e.g., In re DDAVP Direct Purchaser Antitrust Litig.*, 585 F.3d 677, 694-95 (2d Cir. 2009), later proceeding, 903 F. Supp. 2d 198, 214 (S.D.N.Y. 2012) (plaintiffs adequately alleged that the defendant's citizen petition caused actionable delay where the FDA approved plaintiff's ANDA on the same day that it rejected Defendant's citizen petition); *In re Prograf Antitrust Litig.*, No. 1:11-MD-2242-RWZ, 2012 WL 293850, at *7 (D. Mass. Feb. 1, 2012) (denying motion to dismiss where, for causation, the complaint alleged that (1) the FDA approved the plaintiff's ANDA on the same day it rejected the challenged citizen petition; (2) the FDA maintains an informal policy of considering all relevant citizen petitions before approving pending ANDAs; and (3) the FDA made public statements suggesting that its delay in approving the ANDA was "attributable" to the FDA's need to evaluate the challenged

citizen petition); *Spear Pharm., Inc.*, LLC, 610 F. Supp. 2d at 285-288 (finding causation sufficiently alleged where defendant used confidential information to file citizen petition, foreseeably resulting in delayed ANDA approval); *Louisiana Wholesale Drug Co. v. Sanofi-Aventis*, No. 07-CV-7343, 2008 WL169362 at *5 (S.D.N.Y. Jan. 18, 2008) (actionable delay from sham petition based on alleged false health concerns).

At this stage, Amneal need not allege facts disproving every potential cause for delay – it need only allege facts sufficient to support its causes of action, which it has done by alleging that Reckitt’s misconduct delayed Amneal’s ANDA approval and caused lost sales. *See In re Skelaxin Antitrust Litig.*, 2013 WL 2181185, at *16 (plaintiffs are not required to “adduce proofs discrediting all possible intervening causes of the delayed launch of generic products” to satisfy Rule 12); *In re Cardizem CD Antitrust Litig.*, 105 F. Supp. 2d 618, 650 (E.D. Mich. 2000) (plaintiff generic drug manufactures did not have to disprove every “hypothetical possibility” to establish antitrust injury from delayed market entry); *see also In re Flonase Antitrust Litig.*, 798 F. Supp. 2d at 629-30 (FDA’s deficiency notices and generic manufacturer’s search for compliant API did not break the chain of causation originating from the defendant’s citizen petitions); *Spear Pharm., Inc.*, 610 F. Supp. 2d at 280-81 (potential issues with plaintiff’s ANDA would not break the chain of causation originating from the defendant’s citizen petition); *Dr. Reddy’s Labs., Ltd. v. aaiPharma Inc.*, No. 01-cv-10102, 2002 WL 31059289, at *10-11 (S.D.N.Y. Sept. 13, 2002) (rejecting defendant’s argument that FDA requests for additional ANDA testing data during the delay period were evidence that ANDA deficiencies, not defendant’s conduct, were the cause of delayed approval). Amneal will prove through discovery that *Reckitt’s conduct*, not any issues with Amneal’s ANDA, caused the delay in approval, resulting in significant lost sales both before and after approval.

Reckitt also erroneously suggests that Amneal must allege a “tentative approval” from the FDA in order to state an actionable delay claim. *See* ECF 212-1 at 12. “Tentative approval” does not apply here. “Tentative approval” letters are issued by the FDA only for ANDAs involving patent or other legal exclusivity. *See id.*; *see also ANDA (Generic) Drug Approvals - Previous Years*, U.S. Food and Drug Administration, <http://www.fda.gov/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/DrugandBiologicApprovalReports/ANDAGenericDrugApprovals/ucm050527.htm> (last visited Apr. 27, 2016) (“A tentative approval is issued to the applicant when the application is approvable prior to the expiration of any patents or exclusivities accorded to the reference listed drug product.”). Indeed, the cases cited by Reckitt in support of its position all involve so-called “Paragraph IV” litigation between brand and generic manufacturers over claimed patent exclusivity rights. *See* ECF 212-1 at 12 n.4 (citing, *inter alia*, *Meijer, Inc. v. Biovail Corp.*, 533 F.3d 857, 859 (D.C. Cir. 2008)). Here, Reckitt’s orphan drug exclusivity on tablets expired in 2009, prior to Amneal’s ANDA, so the FDA would not have issued a “tentative approval.”⁹

Finally, Reckitt argues that the delay must be caused “*solely* because of” the alleged misconduct. ECF 212-1 at 10 (emphasis added). But a plaintiff need only allege that defendant’s conduct was a “material cause” of its injury, not the *sole* cause. *See, e.g., In re Flonase Antitrust Litig.*, 798 F. Supp. 2d at 627 (citing *Am. Bearing Co. v. Litton Indus., Inc.*,

⁹ Reckitt also cites inapposite case law involving summary judgment or in which the generic sponsor failed to allege any effort to obtain approval in support of its claim. *See Meijer*, 533 F.3d at 860, 862 (granting summary judgment where the plaintiff was not “prepared” to enter the relevant market due to substantive product development issues preventing it from obtaining FDA approval for a full year after defendant’s allegedly anticompetitive conduct ceased); *Brotech Corp. v. White Eagle Int’l Techs. Grp., Inc.*, No. CIV.A.03-232, 2004 WL 1427136, at *6 (E.D. Pa. June 21, 2004) (plaintiff’s filings contained “no allegations” about FDA approval other than “simply alleg[ing] that such approval must be obtained and that [Plaintiff was] seeking such regulatory approval[.]”).

729 F.2d 943, 952 (3d Cir. 1984)) (antitrust causation “requires a plaintiff to show that the defendant’s antitrust violation was a ‘material cause’ of the plaintiff’s injury.”); *McDonough v. Toys R Us, Inc.*, 638 F. Supp. 2d 461, 483 (E.D. Pa. 2009) (“It is enough that the illegality is shown to be a material cause of the injury; a plaintiff need not exhaust all possible alternative sources of injury in fulfilling his burden of proving compensable injury[.]”); *In re Wellbutrin SR/Zyban Antitrust Litig.*, 281 F. Supp. 2d 751, 756-57 (E.D. Pa. 2003) (citing 2 PHILLIP E. AREEDA & HERBERT HOVENKAMP, ANTITRUST LAW ¶ 338(a) at 317 (2d ed. 2000) (finding plaintiff’s inability to get FDA approval was not an independent cause where defendant’s anticompetitive conduct may have partially caused that delay; “to require proof that the illegal conduct was the exclusive cause of the plaintiff’s injury would effectively deny private remedies, because multiple causes always affect everyone.”)).

Thus, Amneal has sufficiently pleaded that Reckitt’s conduct caused delay injury.

4. Amneal States An Actionable Lanham Act Claim.

Lastly, Reckitt’s Rule 12 challenge to Amneal’s Lanham Act claim for false advertising should be denied. As set forth below, Amneal’s Complaint properly pleads facts showing that Reckitt engaged in false advertising by claiming, both explicitly and implicitly, that (a) Suboxone film is safer than Bu-Na tablets, and (b) Bu-Na tablets are, standing alone, unsafe. *See, e.g.*, Compl. ¶¶ 115–16, 118.

To be actionable under the Lanham Act, the Third Circuit requires that a statement be alleged as “either (1) literally false or (2) literally true or ambiguous, but has the tendency to deceive consumers.” *Groupe SEB USA, Inc. v. Euro-Pro Operating LLC*, 774 F.3d 192, 198 (3d Cir. 2014) (quoting *Novartis Consumer Health, Inc. v. Johnson & Johnson-Merck Consumer Pharm. Co.*, 290 F.3d 578, 586 (3d Cir. 2002)). While Reckitt cites to an outdated offshoot of

law discussing an “intermediate” pleading standard for Lanham Act cases, this District has held that “a Lanham Act allegation requires only that a plaintiff plead sufficient facts to support his allegation . . . and nothing more.” *U.S. ex rel. Knisely v. Cintas Corp.*, 298 F.R.D. 229, 239 (E.D. Pa. 2014) (internal citations omitted).¹⁰

Here, Amneal alleges that Reckitt’s claims about film’s superior safety, and the unsafety of Bu-Na tablets, were both literally false and had a tendency to deceive consumers. For instance, Amneal alleges that the safety “benefits” of Suboxone film over tablets, such as “fewer partial doses left in open pouches where children might access them,” are “literally false.” Compl. at ¶ 115. Amneal cites and quotes specific facts – including FDA findings relating to the safety superiority claim, and Reckitt’s claim that tablets are “unsafe” – demonstrating the falsity of those claims. *See id.* at ¶¶ 103-108, 116, 118.

As Amneal alleges, “Reckitt obtained FDA approval for Suboxone film based almost entirely on previous studies that Reckitt used to demonstrate the safety and efficacy of the tablets.” Compl. at ¶ 103. Further, in a General Advice Letter, the FDA specifically rejected Reckitt’s claim of reduced pediatric exposure due to fewer partial doses in open pouches:

[W]e do not agree that the packaging for buprenorphine HCl and naloxone HCl sublingual film provides meaningful incremental protection against pediatric exposure. . . . *Because patients are known to divide tablets, it may be expected that patients will remove films from the package and*

¹⁰ Reckitt cites to a doctrine first articulated in *Max Daetwyler Corp. v. Input Graphics, Inc.*, 608 F. Supp. 1549, 1556 (E.D. Pa. 1985), in which the complaint merely recited the form allegation that defendants had “falsely advertised the quality and nature” of their product. *Id.* at 1554. However, as Reckitt concedes, and as courts in this District have noted, “for the most part, those courts applying [*Max Daetwyler*’s] intermediate pleading standard to Lanham Act claims adopted it before *Iqbal* and *Twombly*.” *U.S. ex rel. Knisely*, 298 F.R.D. at 238-39. *See also Groupe SEB USA, Inc. v. Euro-Pro Operating LLC*, No. CIV.A. 14-137, 2014 WL 1316039, at *4 (W.D. Pa. Apr. 1, 2014) (“Moreover, as other district courts in this circuit have observed, the standard set forth in *Max Daetwyler* was decided prior to the Supreme Court’s decisions in *Twombly* and *Iqbal* as well as the Third Circuit’s decision in *Fowler*.”).

have partial doses that are neither in the child-resistant pouch nor in a child-resistant medication bottle.

Id. at ¶ 104. The FDA further noted that Suboxone film presents an additional risk of pediatric exposure: “because the film cannot be spit out (unlike a tablet) it is possible that a child who obtains access to even one dose might be more adversely affected than a child who obtains access to a single tablet.” *Id.* at ¶ 105. This particular risk implicates Reckitt’s claim that faster dissolution improves safety because, upon introduction into the mouth, Suboxone film hydrates to a gel within approximately thirty seconds, and erodes completely over the course of three minutes, releasing all of the buprenorphine. *Id.* In contrast, Suboxone tablets have a much longer oral residence time (each tablet may take up to ten minutes to dissolve), and may be spit out, terminating the exposure to buprenorphine. *Id.*

In addition, as alleged, the FDA rejected the studies employed by Reckitt in an attempt to make demonstrations of superior safety of the film over the tablet, finding:

- “Almost all of the safety experience with the proposed new formulation was derived from a single study. This study had a number of flaws, including inadequate training of personnel conducting the safety exams, inconsistent recording of findings, treatment of participants with dosing regimens not recommended in the proposed labeling, and a high drop-out rate”;
- “After review of the clinical study report and database for the study RB-US-07-0001 [used to support Reckitt’s NDA for Suboxone film], our overall conclusion is that the study was poorly designed and conducted and was not useful for demonstrating any difference in the safety profile or abuse potential of the two formulations”;
- “There was no positive control arm (Suboxone tablet group) in this study. So, it would be impossible to claim any potential advantages of Suboxone strip [film] over the current Suboxone tablet product.”

Id. at ¶ 106.¹¹ Accordingly, given the facts alleged, Reckitt’s discussion of the relative merits of the two delivery mechanisms are inappropriate for a Rule 12 motion.

Further, Reckitt’s noisy announcement that it would withdraw tablets on that basis that they were “unsafe” due to their packaging was communicated to patients and health care providers, constituting part of a “deceptive marketing campaign.” *Id.* at ¶ 112. The falsity of that claim is found in the FDA’s denial of the Citizen Petition, which expressly rejected Reckitt’s claims that tablets were unsafe and that Reckitt was withdrawing its product for reasons of safety. *See id.* at ¶¶ 93, 100.

Reckitt argues that Amneal fails to sufficiently plead facts showing consumer deception based on a preliminary injunction decision, *Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222, 226 (3d Cir. 1990). But this argument does not deal with literal falsity, and Reckitt fails to acknowledge *Novartis*, which explicitly abrogated the very point in *Sandoz* upon which Reckitt relies, and held that unsubstantiated advertising is “*per se* false”:

Today we decide what we left open in *Sandoz*. We hold that, although the plaintiff normally has the burden to demonstrate that the defendant’s advertising claim is false, a court may find that a completely unsubstantiated advertising claim by the defendant is *per se* false without additional evidence from the plaintiff to that effect.

290 F.3d at 590. As *Novartis* explained, quoting *Sandoz*, “[a] Lanham Act plaintiff may be permitted to presume that consumers expect advertisers to have at least some semblance of support for their publicly-disseminated claims.” *Id.* at 589-90 (quoting 902 F.2d at 228).

¹¹ Amneal has also pleaded facts showing that the film product creates public safety concerns involving abuse and diversion. For example, in reviewing Reckitt’s NDA for the film formulation, the FDA found “that expanded use of this product will result in significant abuse and diversion that needs to be considered with any anticipated benefits the drug may offer.” Compl. at ¶ 107. This is attributable to the fact that the film version is easier to conceal than tablets, as Reckitt learned when almost 6,000 film strip packets went missing after the limited clinical studies Reckitt performed to gain FDA approval. *Id.*

Thus, Reckitt's arguments concerning the need to evaluate consumer perception at this stage miss the mark. For instance, Amneal alleges, including quotes from the FDA's prior findings regarding film superiority on safety, that Reckitt's studies were entirely unsubstantiated. *See* Compl. at ¶¶ 103-108, 116, 118. Similarly, as the FDA found, the study that Reckitt offered in support of its claim that tablets were "unsafe" due to packaging expressly acknowledged that the impact of packaging on pediatric exposures "was not evaluated, and that definitive conclusions about these measures could not be reached. . . ." *Id.* at ¶ 98. These allegations support claims of literal falsity and the test set forth in *Novartis* for purposes of Rule 12.

Reckitt also argues that Amneal has not adequately "identif[ied] when or how [the false statements] were allegedly used, or identify to whom they were allegedly distributed." ECF 212-1 at 22. But Amneal specifically alleges that "Reckitt has caused and continues to cause its false and misleading advertising to enter interstate commerce, including by making false and misleading claims in national Internet advertising and, on information and belief, through direct advertising to medical professionals and their patients." Compl. at ¶ 138. This allegation is necessarily broad, given the unique nature of the advertising at issue and is sufficient at this stage: Reckitt communicated its false and misleading claims to prescribers directly and non-publicly. Discovery will shed further light on the particulars of Reckitt's false advertising.

Finally, Reckitt's case citations are unpersuasive. Unlike in *Master Cutlery, Inc. v. Panther Trading Co.*, Amneal has articulated false statements made by Reckitt and identified the forms in which they were disseminated, including through the Citizen Petition as delivered to doctors and via direct ads to patients. No. CIV.A. 12-4493 JLL, 2013 WL 4517860, at *5 (D.N.J. Aug. 26, 2013) (noting that counter-plaintiff failed to identify the "nature" of alleged statements). And unlike in *Crestron Electronics, Inc. v. Cyber Sound & Security Inc.*, Amneal

has identified the text and context behind statements made by Reckitt to patients and health care providers. No. CIV. 11-3492 FSH MAH, 2012 WL 426282, at *11 (D.N.J. Feb. 9, 2012) (“Cyber Sound does not allege that Crestron actually made any of the statements listed . . . to any of the customers listed . . .”). Reckitt will have the opportunity to seek to substantiate these claims through discovery, but for purposes of Rule 12, Amneal has sufficiently pleaded false advertising under the Lanham Act.

CONCLUSION

Based on the foregoing, Amneal respectfully requests that the Court deny Reckitt’s Partial Motion to Dismiss aspects of Amneal’s Sherman Act claim and the Lanham Act claim. To the extent that the Court finds any deficiencies in Amneal’s complaint, Amneal respectfully requests leave to amend under Fed. R. Civ. P. 15.

Dated: April 29, 2016

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CERTIFICATE OF SERVICE

I hereby certify that on April 29, 2016, I electronically filed the foregoing Opposition to Indivior Inc.'s Partial Motion to Dismiss with the Clerk of the Court using the CM/ECF System which will then send a notification of such filing to all counsel of record.

/s/ William D. Coston

William D. Coston